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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,630	06/13/2001	Gary R. Dulak	ADIV-1790-AU	3325

7590 10/27/2005

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EXAMINER
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SIRMONS, KEVIN C

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 10/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/882,630	Applicant(s) DULAK ET AL.	
	Examiner Kevin C. Sirmons	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 10, 12-14 and 21-31 is/are pending in the application.
- 4a) Of the above claim(s) 24-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10, 12-14, 21-23, 28, 29 and 31 is/are rejected.
- 7) ☒ Claim(s) 30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/14/05; 6/18/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 24-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/10/05. Applicant provisionally elects Group II, claims 10, 12-14 and 21-31 and Species III as shown in figs. 7-9. Applicant indicated that claims 10, 12-14, 21-23 and 28-31 are readable thereon.

### ***Claim Objections***

Claim 13 objected to because of the following informalities: Claim 13 appears to be incomplete. Therefore, it cannot be examined. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 12, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devonec U.S. Pat. No. 6,290,666 in view of Minter U.S. Pat. No. 3,332,424.

Devonec discloses a method for inserting a medical instrument into a urethra, comprising:

Providing a urethral access device having an elongate tube with a lumen extending along an axis between a proximal end and a distal end, and a handle at the proximal end of the tube (63); configuring the handle with a distally-facing, and proximally facing surface, the distally-facing surface sized and configured to receive two adjacent fingers of a user's hand (63); inserting the distal end of the tube into the urethra to an operating position in order to provide access for the medical device (figs. 9 and 10); moving the medical instrument distally into the proximal end of the lumen of the tube and through the lumen of the tube into the urethra (figs. 9 and 10); during the moving step creating a distal force on the urethral access device (figs. 9 and 10); and applying a proximal force on the distally-facing surface of the handle to oppose the distal force and maintain the access device in the operative position (fig. 10). Devonec does not disclose a concave surface. Minter discloses a concave surface (fig. 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Devonec to include a concave surface with the concave surface as taught by Minter for improving the handling of the access device.

As to claim 12, once the device of Devonec has been modified, then the proximally facing surface will have a convex configuration. As to claim 14, (63);

### ***Claim Rejections - 35 USC § 103***

Claims 21-23, 28-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al U.S. Pat. No. 6,872,198.

Wilson discloses providing an elongate tube having a working channel (54) and a handle assembly (72) having an engagement apparatus (see threads) adapted to fit over the tube, the handle having a movable relationship with the tube when the engagement apparatus is in a first state and a fixed relationship with the tube when the engagement apparatus is in a second state (figs. 1 and 2); placing the engagement apparatus in the first state; moving the handle to a predetermined location along the tube (figs. 1 and 2); and placing the engagement apparatus in the second state to fix the handle to the tube at the predetermined location and provide the access device with the desired length (figs. 1 and 2). However, Wilson does not disclose removing a portion of the elongate tube to shorten the length of the tube generally to the desired length. It would have been a matter of design choice to vary the length of the tube, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955). As to claims 22 and 23, (70); As to claims 28-29 and 31, (see above rejection and the examiner regards the proximal portion of the handle as a nut).

***Allowable Subject Matter***

Claim 30 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Sirmons whose telephone number is 571-272-4965. The examiner can normally be reached on Monday-Friday 6:30-4:00 ALT FRI.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin C. Sirmons  
Primary Examiner  
Art Unit 3763  
10/26/05

A handwritten signature in cursive script that reads "Kevin C. Sirmons".